ACCESS POINT
MEDICAL

K050280
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APR 1 1 2005

3. SUMMARY OF SAFETY AND EFFECTIVENESS

A. **SPONSOR IDENTIFICATION**

Mr. Patrick Richey
Access Point Medical, L.L.C.
10 Glenville Street
Greenwich, CT 06831

B. **ESTABLISHMENT REGISTRATION NUMBER:** Pending

C. **OFFICIAL CONTACT PERSON**

Norman F. Estrin, Ph.D., RAC
President
Estrin Consulting Group, Inc.
9109 Copenhaver Drive
Potomac, MD 20854
estrin@yourFDAconsultant.com

Tel: (301) 279 -2899
Fax: (301) 294-0126

D. **DATE OF PREPARATION OF THIS SUMMARY:** February 4, 2005

E. **PROPRIETARY (TRADE) NAME:** **AXS-1 Basic Wheelchair**

F. **COMMON NAME:** Wheelchair

G. **CLASSIFICATION NAME:** Wheelchair, mechanical

H. **REGULATION NUMBER:** 21 CFR 890.3850

I. **PROPOSED REGULATORY CLASS:** Class I

J. **DEVICE PRODUCT CODE:** IOR

K050280
2/2

K. **MEDICAL SPECIALTY:** Physical Medicine

L. **DESCRIPTION OF DEVICE**

The Access Point Medical **AXS-1 Basic Wheelchair** is a wheelchair that provides mobility to persons limited to a sitting position. It consists of rigid, mechanical, steel frame and leatherette or nylon upholstery that meets EN102-1: Assessment of the Ignitability of Upholstered Furniture. It has two 24" rear wheels and two 8" front casters for turning and maneuverability. The Access Point Medical Transport Series Transport Chair is intended for use indoors and outdoors, over smooth surfaces (all standard indoor flooring surfaces, concrete, asphalt and packed dirt) that are free of large obstacles and inclines greater that 9 degrees.

INDICATIONS FOR USE: The **AXS-1 Basic Wheelchair** is indicated for providing mobility to persons limited to a sitting position

N. **PREDICATE DEVICE**: Jiangsu Intco Medical Equipment & Supply Co., Ltd. EZ-4000 Series (K002669).

O. **COMPARISON OF TECHNOLOGICAL CHARACTERISTICS:**

The **AXS-1 Basic Wheelchair** and the Jiangsu Intco Medical Equipment & Supply Co., Ltd. EZ-Light 4000 series (K002669) are substantially equivalent products in all areas impacting safety and effectiveness.

P. **TECHNOLOGICAL CHARACTERISTICS SUMMARY:**

Access Point Medical wheelchair production meets the following standards:

ISO 7171-1 Wheelchair: Determination of static stability
ISO 7176-3 Wheelchair: Determination of efficiency of brakes
ISO 7176-8 Wheelchair: Requirements and test methods for static, impact and fatigue strengths
ISO 7176-11 Wheelchair: Test dummies
ISO 7176-15 Wheelchair: Requirements for information disclosure, documentation and labeling.
ISO 7176-16 Wheelchair: Resistance of ignition of upholstered parts – Requirements and test methods
EN 1021-1 Furniture – Assessment of the Ignitability of Upholstered Furniture

Q. **CONCLUSION**

Access Point Medical **AXS-1 Basic Wheelchairs** conform fully to the standards which are mentioned in Section P as well as applicable 21 CFR references, and meets pinhole FDA requirements, biocompatibility requirements and labeling claims required by these standards. There are no safety/efficiency issues or claims that differ from the predicate devices cited.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 1 1 2005

Dr. Norman F. Estrin Ph.D., RAC
President
Estrin Consulting Group, Inc.
9109 Copenhaver Drive
Potomac, Maryland 20854

Re: K050280
Trade/Device Name: AXS-1 Basic Wheelchair
Regulation Number: 21 CFR 890.3850
Regulation Name: Mechanical wheelchair
Regulatory Class: I
Product Code: IOR
Dated: March 24, 2005
Received: March 24, 2005

Dear Dr. Estrin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120 . Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Miriam C. Provost, Ph.D.
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): **K050280**

Device Name: **AXS-1 Basic Wheelchair**

1. Indications for Use: **AXS-1 Basic Wheelchair** is indicated for providing mobility to persons limited to a sitting position.

Prescription Use _____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ✓ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

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510(k) Number K050280